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EXAMINER

SZMAL, BRIAN SCOTT

ART UNIT	PAPER NUMBER
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3736

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/528,417

Applicant(s)

WIEGERINCK ET AL.

Examiner

Brian Szmaj

Art Unit

3736

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20 and 22-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20 and 22-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 March 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/808)
- Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 24, 2008 has been entered.

Claim Objections

2. Claim 22 is objected to because of the following informalities: In line 2, "opening" should read as "openings". Appropriate correction is required.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 20 and 22-34 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 20 and 31 have been amended to include a method step within apparatus claims. Both Claims 20 and 31 have been amended to state "said rigid tube in operation providing a closure in the body cavity for said flushing solution when expelled". The claims should be amended to claim the rigid tube provides a closure in the body cavity, in order to overcome the rejection.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 22 and 30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 20 was amended to include the use of a central opening surrounded by a plurality of sampling openings. Claim 22 claims an additional opening for expelling fluid adjacent to the sampling openings. The specification fails to support an opening in addition to the central opening and the sampling openings.

Claim 30 discloses a biasing means for the plunger. Claim 20, however is based on the embodiment as shown in Figures 3 and 4 of the current application and the biasing means is shown in Figures 5 and 6. The specification fails to support the use of a biasing means with any of the other embodiments as shown in the current figures.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear to the Examiner if the claimed opening is an additional opening to the number of sampling openings and the central opening as claimed in Claim 20. It appears that the claim should read the central opening is for expelling a liquid adjacent the number of sampling openings.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 20, 22-28, 31, 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ayre (3,540,432) in view of Mendoza et al (6,071,231) in view of Suzuki et al (4,781,699).

Ayre discloses a cytological sampling instrument and further discloses a tubular means for insertion into a body cavity, the tubular means has a curved distal end, a storage means connected to the tubular means and a vacuum means connected to the storage means and tubular means, the tubular means has a diameter of at least 1cm and has openings only at the curved distal end; a liquid containing means and pump means for expelling the liquid at the distal end of the device; the storage means comprise the liquid containing means; the liquid means has a volume of less than 10cc; a sealing means for sealing the openings; the liquid containing means contains a flushing solution (the glycerine solution acts as a flushing solution when expelled from

the device when placed at the cervix); the flushing solution is expelled from the device and a sample is introduced in the device. See Column 3, lines 7-10, 17-21, 38-45 and 65-68; and Column 4, lines 7-12 and 38-41.

Ayre and Suzuki et al however fail to disclose the rigid tube provides a closure in the body cavity for a flushing solution when expelled; and the tube further comprises a number of sampling openings only at the curved introduction end, wherein the number of sampling openings comprises a central opening.

Mendoza et al disclose a means for artificial insemination and further disclose the rigid tube provides a closure in the body cavity for a flushing solution when expelled; and the tube further comprises a number of sampling openings only at the curved introduction end, wherein the number of sampling openings comprises a central opening. See Figures 4 and 5.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Ayre to include a closure in the body cavity when the flushing fluid is expelled, and a number of sampling openings around a central opening, as per the teachings of Mendoza et al, since it would provide a means of preventing the tube from dislodging from the location during flushing, as well as concentrating all of the flushing and sampling at the very distal end of the device.

Ayre and Mendoza et al however fail to disclose openings that are less than 5mm in diameter; the vacuum means comprise a pump means; the vacuum means comprise a plunger-cylinder; and the tube comprises the cylinder.

Suzuki et al disclose a mucus sampling device and further disclose openings that are less than 5mm in diameter; the vacuum means comprise a pump means (the plunger acts as a pump); the vacuum means comprise a plunger-cylinder; and the tube comprises the cylinder. See Column 2, lines 20-23, 38-44, 64 and 65.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Ayre and Mendoza et al to include the use of small diameter openings as well as a different type of a vacuum source, as per the teachings of Suzuki et al, since it would provide a device that has the ability to obtain a mucus sample utilizing a vacuum source.

10. Claims 29, 30, 32 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ayre (3,540,432), Mendoza et al (6,071,231) and Suzuki et al (4,781,699) as applied to claims 20, 31 and 35 above, and further in view of Lurie et al (7,207,951 B1).

Ayre, Mendoza et al and Suzuki et al, as discussed above, disclose a cervical mucus sampling means, but fail to disclose the vacuum means comprise a plunger in the tubular means, wherein abutment means are provides to define relative movement of the plunger and the tubular means; a biasing means for the plunger; and the flushing solution comprises physiological saline.

Lurie et al, as discussed above, disclose a means for obtaining cell samples and further disclose the vacuum means comprise a plunger in the tubular means, wherein abutment means are provides to define relative movement of the plunger and the tubular means; a biasing means for the plunger; and the flushing solution comprises

physiological saline. See Column 4, lines 2-11 and 63-65; Column 5, lines 44-67; and Column 6, lines 1-4.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Ayre, Mendoza et al and Suzuki et al to include a means of biasing the plunger and utilizing saline as the flush solution, as per the teachings of Lurie et al, since it is well known in the art to utilize a biasing means on the plunger as well as utilizing saline as a flush solution during a medical procedure.

11. Claims 33, 34, 38 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ayre (3,540,432), Mendoza et al (6,071,231) and Suzuki et al (4,781,699) as applied to claims 20, 31 and 35 above, and further in view of Oster (3,815,580).

Ayre, Mendoza et al and Suzuki et al, as discussed above, disclose a means of obtaining a mucus sample, but fail to disclose a kit comprising a closable container for containing the sample, and the container is separate from the sampler; transferring the sample to a container; and the container is provided with a preserving agent.

Oster discloses a means of preserving cytological samples and further discloses a kit comprising a closable container for containing the sample, and the container is separate from the sampler; transferring the sample to a container; and the container is provided with a preserving agent. See Figures 1 and 8.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Ayre, Mendoza et al and Suzuki et al to include a kit with a closable container for containing the sample, as per the teachings

of Oster, since it is well known in the art to obtain a cell sample and place the sample within a fixative for shipping to a lab.

Response to Arguments

12. Applicant's arguments with respect to claims 20 and 22-39 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmaj whose telephone number is (571)272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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